

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Jan Andersson et al.	Art Unit	: 3772
Serial No.	: 10/673,689	Examiner	: Nihir Patel
Filed	: September 29, 2003	Conf. No.	: 1299
Title	: INHALATION DEVICE		

**Mail Stop Appeal Brief - Patents**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**BRIEF ON APPEAL**

Appellants are appealing the final rejection of claims 34-39, 41 and 73 in the Office Action dated March 13, 2008, and the Advisory Action dated July 17, 2008. A Notice of Appeal was filed and received by the U.S. Patent and Trademark Office on July 30, 2008.

**(1) Real Party in Interest**

The Real Party in Interest is AstraZeneca AB, the assignee of record, which is a subsidiary of AstraZeneca PLC.

**(2) Related Appeals and Interferences**

There are no prior or pending related appeals, judicial proceedings, or interferences.

**(3) Status of Claims**

Claims 1-33, 42-54, and 65-72 are canceled. Claims 55-64 have been allowed and claim 40 has been objected to as being dependent upon a rejected base claim.

Claims 34-39, 41 and 73 stand rejected and are under appeal herein.

Claims 34-39, 41 and 73 stand rejected under 35 U.S.C. 102(b) as being anticipated by Coccozza (U.S. Patent No. 5,033,463).

**(4) Status of Amendments**

All amendments have been entered.

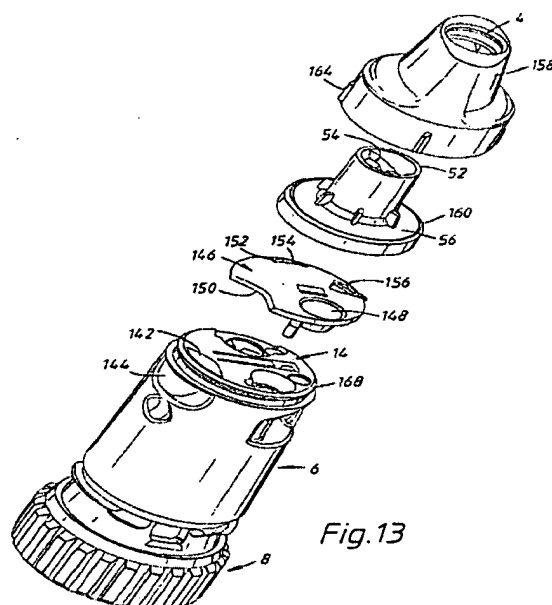
### (5) Summary of Claimed Subject Matter

The claims are directed to a powder inhaler for administering powder by inhalation.

Claims 34, 35 and 73 are the independent claims.

The powder inhaler of **independent claim 34** includes a dosing unit (e.g., 16, FIG. 2) for providing a dose of powder, and a flow path (e.g., chamber 58, FIG. 5) downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is drawn on inhalation by a user.

An example of a powder inhaler embodying the claimed invention is shown in FIG. 13 of Appellants' application, reproduced below:



The powder inhaler is characterized in that at least one of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path (e.g., cover plate 146 and part 160 of the mouthpiece). The inhaler also includes a powder dislodging member (e.g., member 156) which is fixed in position relative to one of the at least one surface or at least one other of the surfaces of the flow path (e.g., member 156 is formed integrally with cover plate 146). The powder dislodging member is also configured such that on relative movement of the at least one surface and at least one other of the surfaces of the flow path (e.g., rotation of part 160 relative to member 156), the powder dislodging member contacts the other of the at least one

surface or at least one other of the surfaces of the flow path (member 156 contacts the lower surface of the flange 56 of part 160) such as to dislodge powder accumulated on the surface. See, e.g., paragraph [0048] of Appellants' published application. The powder dislodging member includes a scraper or a brush (see, e.g., lines 19-21 of paragraph [0048]). Further support for independent claim 34 can be found in Appellants' specification as originally filed, e.g., at page 4, lines 5-10; page 8, lines 7-14; page 9, lines 25-26; page 16, lines 18-22; and in original claims 1-3, 8 and 9.

The powder inhaler of **independent claim 35** includes a dosing unit for providing a dose of powder and a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder in use is drawn on inhalation by a user. The powder inhaler is characterized in that the inhaler further comprises a scraper (e.g., member 156) which is movable relative to at least one of the surfaces of the flow path (e.g., part 160, as discussed above) and is configured, on movement of the scraper relative to at least one of the surfaces of the flow path, to contact at least one of the surfaces of the flow path (e.g., the lower surface of flange 56 of part 160) such as to dislodge powder accumulated on the surface. Support for independent claim 35 can be found as discussed above.

The powder inhaler of **independent claim 73** includes a dosing unit for providing a dose of powder, and a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user. The inhaler further comprises a brush (e.g., member 156, see e.g., lines 19-21 of paragraph [0048], which state that member 156 may be a brush) which is movable relative to at least one of the surfaces of the flow path and is configured, on relative movement thereof relative to the at least one of the surfaces of the flow path, to contact the other of the at least one of the surfaces of the flow path such as to dislodge powder accumulated thereon. Support for independent claim 35 can be found as discussed above.

#### **(6) Grounds of Rejection to be Reviewed on Appeal**

Claims 34-39, 41 and 73 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cocozza (U.S. Patent No. 5,033,463.) Appellant requests reversal of this rejection.

(7) **Argument**

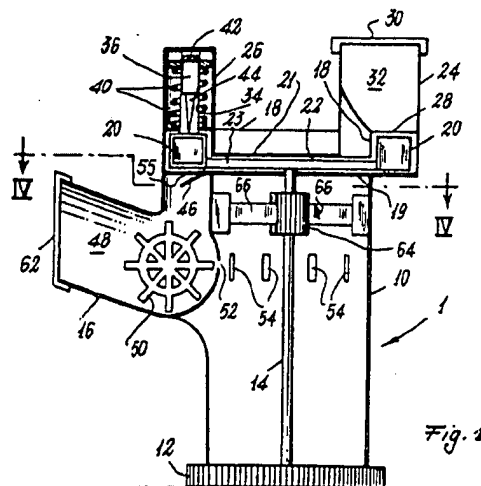
Appellant will explain why the currently pending rejection should be reversed.

Claims 34-39, 41 and 73 Are Novel Over Cocozza Under 35 U.S.C. 102(b)

Appellants' claims require that a surface of the flow path (claim 34) or the scraper (claim 35) or brush (claim 73) be "configured...to contact the at least one of the surfaces of the flow path such as to dislodge powder accumulated thereon." This contact allows accumulated powder to be dislodged from surfaces of the flow path on which the powder has accumulated. It is necessary that one surface of the flow path, e.g., the scraper or brush, contact another surface of the flow path on which powder is accumulated, e.g., the wall of the flow path, in order to sweep the surface and thereby remove adhered powder with a scraping or brushing action. At issue is whether Cocozza discloses a device in which a surface of the flow path, or a scraper or brush, is "configured...to contact the at least one of the surfaces of the flow path such as to dislodge powder accumulated thereon."

There is no indication that any structure described by Cocozza is configured to contact a surface of the flow path such as to dislodge powder accumulated thereon. The Examiner has asserted that the devices provided by Cocozza to disintegrate agglomerates read on Appellants' claimed powder dislodging devices. Appellants respectfully disagree.

Cocozza discloses that the disintegrating device "can be of rotatable type (such as a rotatable impeller) or of fixed type (such as a fixed helical element)." (Cocozza, col. 4, lines 48-50.) These alternatives are shown in FIGS. 1 and 10, respectively. The rotatable impeller, shown in FIG. 1, will be discussed first. FIG. 1 is reproduced below:



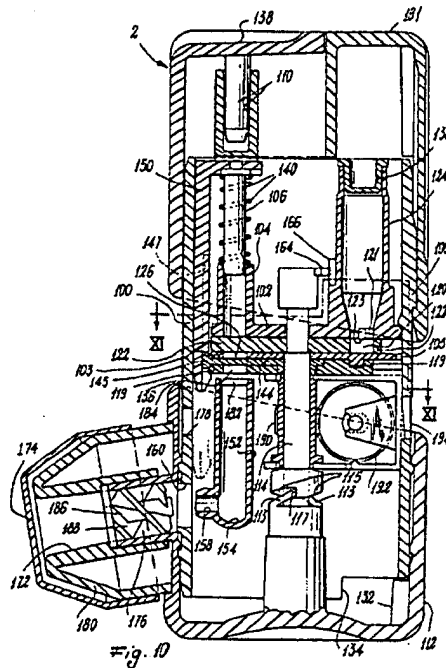
The rotating impeller 50 shown in FIG. 1 clearly does not contact the wall of the flow path. Appellants note the clearance that is shown between the vanes of the impeller and the adjacent wall. This clearance is necessary because if the impeller were to contact the wall it would not be rotatable in the flowing air. It is the purpose of the impeller (or helical element) in Coccozza to disintegrate agglomerates that are entrained with the flowing air during inhalation by a patient. (See, e.g., col. 10, lines 8-10 and 38-42.) Thus, it would be contrary to the stated function of Coccozza if the impeller were to contact the wall, since this contact would interfere with or prevent activation of the impeller by the patient's breath.

Moreover, it is well known in the mechanical arts that an impeller is a rotating component that is positioned to rotate freely inside a casing, e.g., a tube or conduit, to increase the pressure and flow of a fluid passing through the casing. (In Coccozza's device, the impeller serves to create sufficient air pressure to break up the agglomerates of medicament in the airstream.) While there is typically a close fit between an impeller and its casing, sufficient clearance is provided to allow the impeller to rotate. Thus, it is understood by those of skill in the mechanical arts that, in order for an impeller to function properly, the impeller must not contact the inner wall of the tube in which it is positioned. The term "impeller" is used in Coccozza in a manner that is consistent with this commonly understood meaning.

The Examiner states, in the Advisory Action mailed July 17, 2008, that the Examiner disagrees with Appellants' argument that if the impeller were to contact the wall it would not be rotatable in the flowing air. The Examiner states that: "[w]hen looking [at the] applicant's invention particularly figure 13 and pages 13 and 14 (sic). The applicant inherently defines an impeller which does contact the wall. Therefore, the rotatable impeller of the reference contacts the wall as well." Appellants respectfully submit that there is nothing shown in FIG. 13 of Appellants' application that could reasonably be construed as an impeller as that term is used in the art. Like Coccozza's inhaler, the inhaler shown in FIG. 13, reproduced above, includes a deagglomerating device. However, in the inhaler shown in FIG. 13 spirally or helically shaped projections 54 are used to deflect the air drawn therethrough and thereby deagglomerate any larger particles of entrained powder, as discussed in paragraph [0009] of Appellants' specification. These projections are fixed within tubular section 52, and thus cannot reasonably be interpreted as an impeller that contacts the wall. Nor can the member 156, discussed above,

be considered an impeller, as the cover plate 146 on which it is formed does not rotate at all; instead, the part 160 rotates with the mouthpiece 2 relative to the stationary cover plate 146.

Nor is Cocozza's fixed helical element 188, shown in FIG. 10, reproduced below, configured to contact the flow path in the manner recited in Appellants' claims.



The helical element 188 cannot be properly interpreted as a scraper or brush as recited in Appellants' claims at least for the reason that the helical element 188 is fixed so as to define a helically extending channel 176 (see col. 10, lines 8-15). The helical element is not movable *at all*, and thus it cannot be construed to be "configured on relative movement of the at least one and one other of the surfaces of the flow path, to contact the other of the at least one or at least one other of the surfaces of the flow path," as required by Appellants' claims.

Nor is there any indication in Cocozza that any other part of the Cocozza device would be capable of dislodging powder accumulated on a surface of the flow path, as required by Appellants' claims. Dislodging of accumulated powder is not Cocozza's intent; instead, Cocozza is concerned only with disintegrating agglomerations in the medicament to be inhaled, which agglomerates are *entrained with the flowing air*. (See, e.g., col. 10, lines 8-10 and 38-42.)

Applicant : Jan Andersson et al.  
Serial No. : 10/673,689  
Filed : September 29, 2003  
Page : 7 of 12

Attorney's Docket No.: 06275-0131002 / DX 1721-2P  
US

Disintegrating agglomerations during inhalation is a very different function from dislodging powder accumulated on surfaces of the flow path.

With regard to claim 73, Appellants maintain that, in addition to the reasons advanced above, claim 73 is patentable because Coccozza's helical element or rotating impeller cannot reasonably be interpreted as a brush.

In view of the above, Appellants respectfully request withdrawal of the rejection and allowance of all claims.

Please apply the \$510 brief fee and any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 06275-0131002.

Respectfully submitted,

Date: September 24, 2008

/Celia H. Leber/  
Celia H. Leber  
Reg. No. 33,524

Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110  
Telephone: (617) 542-5070  
Facsimile: (877) 769-7945

### Appendix of Claims

34. A powder inhaler for administering powder by inhalation, comprising:

a dosing unit for providing a dose of powder; and

a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user;

characterized in that at least one of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path and in that the inhaler further comprises a powder dislodging member which is of fixed position relative to one of the at least one or at least one other of the surfaces of the flow path and is configured on relative movement of the at least one and one other of the surfaces of the flow path, to contact the other of the at least one or at least one other of the surfaces of the flow path such as to dislodge powder accumulated thereon,

wherein the powder dislodging member comprises one of a scraper or a brush.

35. A powder inhaler for administering powder by inhalation comprising;

a dosing unit for providing a dose of powder; and

a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user;

characterized in that the inhaler further comprises a scraper which is movable relative to at least one of the surfaces of the flow path and is configured, on movement



thereof relative to the at least one of the surfaces of the flow path, to contact the at least one of the surfaces of the flow path such as to dislodge powder accumulated thereon.

36. The inhaler according to claim 35, wherein the at least one of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path and the scraper is of fixed position relative to the at least one other of the surfaces of the flow path.
37. The inhaler according to claim 35, wherein the flow path includes a chamber which includes an inlet and an outlet.
38. The inhaler according to claim 37, wherein the at least one of the surfaces of the flow path defines at least part of the chamber.
39. The inhaler according to claim 38, wherein the at least one and the at least one other of the surfaces of the flow path define at least in part opposed surfaces of the chamber and include the inlet and the outlet thereto.
41. The inhaler according to claim 35, further comprising a mouthpiece which includes one of the at least one or at least one other of the surfaces of the flow path.
73. A powder inhaler for administering powder by inhalation, comprising:

a dosing unit for providing a dose of powder; and

a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user;

characterized in that the inhaler further comprises a brush which is movable relative to at least one of the surfaces of the flow path and is configured, on relative movement thereof relative to the at least one of the surfaces of the flow path, to contact the other of the at least one of the surfaces of the flow path such as to dislodge powder accumulated thereon.

Applicant : Jan Andersson et al.  
Serial No. : 10/673,689  
Filed : September 29, 2003  
Page : 11 of 12

Attorney's Docket No.: 06275-0131002 / DX 1721-2P  
US

### **Evidence Appendix**

None.

Applicant : Jan Andersson et al.  
Serial No. : 10/673,689  
Filed : September 29, 2003  
Page : 12 of 12

Attorney's Docket No.: 06275-0131002 / DX 1721-2P  
US

**Related Proceedings Appendix**

None.